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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,980

02/11/2004

Muraleedharan G. Nair

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EXAMINER

PRATT, HELEN F

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

05/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,980	<b>Applicant(s)</b> NAIR, MURALEEDHARAN G.	
	<b>Examiner</b> Helen F. Pratt	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann (6231866) in view of Walker et al. (5,525,341) and Howell et al. (6,720,353).

Mann discloses a dried composition containing pomace (pulp) and juice from cranberries (a berry) (abstract). Claims 1 and 3 differ from the reference in that the acids and sugars have not been removed from the juice. However, Walker discloses a cranberry juice extract from which simple sugars and acid have been removed (abstract). Howell et al. disclose extracts from the Rosaceae (cherry family) (also claim 4) and cranberry containing juice from which sugars and acids were removed (abstract and col. 15, lines 15-30). The extract can be added to foods such as dried cranberries, fruit pieces or other foods (cranberries contain pulp) (col. 26, lines 24-28). No weight is given at this time to the limitation that the extract is dry as the claimed composition of the reference is to a dried product, free flowing supplement, i. e. a powder (abstract of Mann). Also, the composition can contain a pharmaceutically acceptable carrier and the extract (col. 22, lines 30-39). Claims 1 and 2 further require that the acids and sugars be removed by a particular method and that the other bioflavonoids are eluted in a particular manner and dried by a particular method. These are considered to be

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product by process limitations. However, no weight is given to the method of making in a composition claim. The fact that the procedures of the reference are different than that of applicant is not a sufficient reason for allowing the product-by-process claims since the patentability of such claims is based upon the product formed and not the method by which it was produced. See *In re Thorpe* 227 USPQ 964. The burden is upon applicant to submit objective evidence to support their position as to the product-by-process claims. See *Ex parte Jungfer* 18 USPQ 2D 1796. It would have been obvious to use the acid and sugar extracted cranberry juice of Walker or Howell et al. in place of the unextracted juice of Mann in a composition containing pulp for the function of further nutritive enrichment particularly as Howell et al. disclose that her extract can be used with a carrier in admixture. Also, when applying a known method of removing acid and sugars from juice yields the predictable result of less sugar and acidity. As a dried product has been disclosed, no weight is given to the particular drying process of lyophilization since the results of drying the product are predictable, i. e. a dried product, absent a showing of anything unobvious in using a lyophilized product. Therefore, it would have been obvious to make a composition as disclosed by the combined references.

Claims 1 and 2 have been amended to require that antioxidant or anti-inflammatory activity the composition has antioxidant and anti-inflammatory activity. Since Howell discloses that it is known to isolate proanthocyanin extract antioxidant or anti-inflammatory activity from plants especially fruit and berry plants, and refers to isolating polyphenolic compounds which have the function of being useful in treating

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urinary tract infections, nothing is seen that the polyphenols of Howell et al. or Walker do not have as much antioxidant or anti-inflammatory activity, especially as no particular amounts are claimed. Therefore, it would have been obvious to make a composition containing the claimed ingredients which have antioxidant and anti-inflammatory activity as shown by Howell and Walker in the composition of Mann.

Claim 2 further requires a particular ratio between extracted berry juice and pulp. However, Howell et al. disclose that the amounts of the extract can be from 1 mg to 500 mg per day in tablets and other pharmaceutical compositions and food compositions (col. 13, lines 25-44). Also they can be used in amounts to eliminate symptoms (col. 24, lines 25-30). No criticality is seen in the amount of pulp, which is seen to be only a carrier for the extracted juice and has no nutritional effects. Therefore, it would have been obvious to use the juice and pulp in particular amounts for various functions.

### ARGUMENTS

Applicant's arguments filed 2-27-08 have been fully considered but they are not persuasive. Applicant argues that the reference to Mann does not show a separation of any components of the juice and that pectin is present in the juice. However, applicants claims are open comprising type claims and do not exclude the pectin from the mixture. The additional reference to Howell and Walker disclose that it is known to remove acids and sugars from a juice. Therefore, if one wanted to make a juice with no acids or sugars, it would have been obvious to use the teachings of Howell and Walker to remove the acids or sugars from the juice of Mann. Nothing new is seen that polyphenols and the other ingredients have antioxidant or anti-inflammatory activity, as

this is well known. Also, since the isolation of the claimed ingredients is known, they would inherently have the claimed activity since the claimed ingredients are known to be found in the isolated form.

Applicant argues that the claims now require particular process limitations. As above, the process limitations are not given weight in a composition claim, unless product made by the process is an unobvious product, when compared in a showing to the prior art. Applicant would need to show that a composition made by retaining the bioflavonoids using an adsorption resin and eluting with ethanol, and drying using lyophilization to produce a powder, made a different product than one in which the sugars and acid were removed from the juice, leaving everything else in tact, and this juice was added to the berry pulp.

Applicant argues that Walker et al. "lacks significant amounts of anthocyanins". However, applicants have not claimed any particular amounts of anthocyanins and even so, nothing is seen that since it is known to extract sugar and acids from juice, that there would not be significant anthocyanins in the juice of Walker et al.

Applicants argue that Howell et al. relates to proanthocyanidin compounds. However, the reference was used to disclose that sugars and acids were removed cranberry juice. If the sugars and acids are removed from a berry juice, nothing is seen that the claimed phenolics would not be present in the composition.

Applicant argues that Howell et al. describe a completely different composition since it uses reverse phase lipophilic chromatography to produce the extract. This is not seen since the extract is a proanthocyanidin extract which is seen as being also a

phenolic compound. Nothing is seen that phenolics cannot be eluted using lipophilic chromatography.

In addition, Walker et al. does distinctly disclose an extract which is enriched with polyphenols and flavonoid compounds, which does not contain sugars (abstracts). The reference discloses that the amounts of anthocyanins are present in insignificant amounts (abstract). However, this does not mean that they are entirely lacking and no amounts of anthocyanins are present in the claimed composition.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Helen F. Pratt/

Primary Examiner, Art Unit 1794

Hp 5-7-08